

## REMARKS

### Claim Rejections under 35 U.S.C. § 103.

An invention is unpatentable under 35 U.S.C. § 103(a) ("Section 103") "if the differences between the subject matter sought to be patented over the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains."

To establish a *prima facie* case of obviousness, three criteria must be met. "First, there must be some suggestion or motivation . . . to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." MPEP § 2142.

"Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." *In re John R. Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992). Any such suggestion must be "found in the prior art, and not based on applicant's disclosure." *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). Indeed, "[t]he mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." MPEP § 2142.

A "clear and particular" showing of the suggestion to combine is required to support an obviousness rejection under Section 103. *Id.* For the reasons set forth below, Applicant submits that the relevant prior art fails both to teach or suggest all the claim limitations, and to clearly and particularly suggest the combination indicated by the Examiner; thus, Applicant's claims are not obvious in view of the prior art references.

Claims 1, 7-8, 11-12, 22 and 27 stand rejected under Section 103 as unpatentable over the Noni-now.com advertisements (the “Advertisements”) in view of U.S. Pat. No. 6,136,301 to Pelle (“Pelle”). Claims 1 and 27 stand rejected under Section 103 as unpatentable over U.S. Pat. No. 5,676,949 to Bonte (“Bonte”) in view of Wadsworth (WO 01/15537) and further in view of Fisher (Living Better, vol. 1(5)).

First, Applicant submits that although the Advertisements depict an SPF lip balm containing noni (the “Lip Balm Product”), neither this product nor the composition disclosed in Pelle anticipates nor renders obvious the present invention as neither reference discloses or suggests a lip treatment comprising “*Morinda citrifolia* seed oil [and] *Morinda citrifolia* fruit juice” as recited in independent claim 1 of the present application.

Indeed, the Advertisement features only a lip balm that “gives you the benefits of noni and protection from the sun.” The Advertisement fails to disclose or suggest any particular components of the advertised lip balm.

Similarly, Pelle teaches lipid mixture compositions comprising one or more cholesteryl esters in an amount of at least about 25% by weight of the composition, and less than about 5% by weight of sphingolipid, as well as cosmetic and pharmaceutical formulations for topical application to the lips containing the lipid mixture. Pelle does not teach or suggest a lip balm containing either *Morinda citrifolia* seed oil or *Morinda citrifolia* fruit juice.

Moreover, the Tahitian Noni® Skin Supplement and Tahitian Trim® Plan 40 Body Balance Cream (collectively, the “Skin Products”) also do not render the present invention obvious alone or in combination with the advertised Lip Balm Product or Pelle since the Skin Products are formulated to moisturize and protect the skin generally, and do not mention or suggest beneficial application to the lips. As epidermal skin generally is drastically

physiologically distinct from the physiology of the lips, disclosure of the beneficial effects of noni oil and juice as components of the Skin Products does not inherently suggest the same beneficial effects as applied to the lips.

Indeed, “lips aren’t really skin,” (see [www.lipandlips.com/Lips\\_pages/lips\\_anatomy.htm](http://www.lipandlips.com/Lips_pages/lips_anatomy.htm), visited January 22, 2004) and thus skin products designed for application to the average epidermal surface are generally not well suited for the lips. Specifically, unlike the rest of our skin, lips aren’t protected by a densely packed layer of tissues known as cornified tissue. Lips also lack oil glands, have less pigment than skin, and cannot grow hair. Nerve endings in the lips are very close to the surface, unlike epidermal nerve endings generally, which makes the lips appear pink or red. Finally, lips have the same mucus membrane as the mouth lining and thus are the only part of the body where the inside extends to the outside.

As the combined references fail to mention or suggest a composition for topical application to provide lip care comprising *Morinda citrifolia* seed oil and *Morinda citrifolia* fruit juice, one skilled in the art would not be motivated to combine the references as the Examiner suggests. The Examiner’s rejection thus constitutes an improper hindsight based rejection lacking support in fact as of the present date of invention.

Second, Applicant submits that Bonte, Wadsworth and Fisher, considered cumulatively, do not render claims 1 and 27 obvious as such references neither teach nor suggest the present composition.

Bonte teaches a simaba extract to reduce patchy skin pigmentation, enhance the protective function of the skin or prepare a skin cell culture medium and resulting composition. Bonte lists a mulberry extract as one of thirteen active agents and derivatives thereof that may be included in the simaba extract-containing composition.

Bonte fails to disclose or suggest independent use of a mulberry extract for the purposes disclosed therein. Specifically, Bonte teaches a cosmetic or pharmaceutical composition, especially a dermatological composition, that has a depigmentation activity and an activity promoting keratinocyte differentiation, to reduce patchy skin pigmentation, especially liver spots, treating vitiligo, enhancing the protective function of the skin or improving the appearance of the hair, or for the preparation of a skin cell culture medium as disclosed therein. Bonte neither discloses nor suggests that a mulberry extract may be used independently to obtain such beneficial results. Rather, Bonte emphasizes that a mulberry extract *may be used in conjunction with the requisite simaba extract* to obtain such results.

Applicant respectfully submits that one skilled in the art would not be motivated by Bonte to formulate a product for hydrating and protecting the lips comprising *Morinda citrifolia* derivatives as the only active ingredients. Indeed, Bonte teaches away from such a formulation by emphasizing the predominant importance of the simaba extract in obtaining the above-mentioned results, including “restoring, preserving and/or enhancing the protective function of the skin, especially the water barrier function, and the cohesion of the epidermal cells.” (See col. 2, ln. 56-58).

Similarly, “omission of an element and retention of its function is an indicia of unobviousness.” See MPEP §2144.04(II)(B). Thus, where the present invention protects and hydrates the lips without requiring simaba extract as an element of the composition, the present invention is not obvious in light of Bonte.

In addition, Bonte is properly considered non-analogous art as the compositions disclosed therein are for application to the skin rather than to the lips. As discussed above with reference to the rejections of claims 1, 7-8, 11-12, 22 and 27 in view of the Advertisements and Pelle, “the

lips aren't really skin." See [www.lipandlips.com/Lips\\_pages/lips\\_anatomy.htm](http://www.lipandlips.com/Lips_pages/lips_anatomy.htm). Thus, a composition for application to the skin as disclosed by Bonte solves a problem distinct from the present invention and would likely not motivate one skilled in the art to modify such a composition for application to the lips.

Applicant respectfully submits that the inability of the combined references cited by the Examiner to produce the invention as claimed, and the lack of any suggestion or motivation to modify such art to produce Applicant's invention as claimed renders the present invention non-obvious in view of such references.

As claims 7-8, 11-12, 22 and 27 add further limitations to otherwise allowable subject matter, such claims are also not rendered obvious by the cited references.

Accordingly, Applicant respectfully requests withdrawal of the rejections of claims 1, 7-8, 11-12, 22 and 27 as obvious in view of the cited references under Section 103.

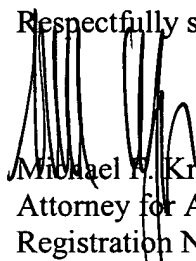
CONCLUSION

Based on the foregoing, Applicant believes that the claims of the present invention are in condition for allowance and respectfully requests the same.

Should the Examiner have any questions, comments, or suggestions in furtherance of the prosecution of this application, the Examiner is invited to initiate a telephone interview with undersigned counsel.

DATED this 26 day of January, 2004.

Respectfully submitted,



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